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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/826,736	04/16/2004	James R. Matson	3154/113	1355

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EXAMINER	
DEAK, LESLIE R	

ART UNIT	PAPER NUMBER
3761	

MAIL DATE	DELIVERY MODE
04/17/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/826,736	MATSON ET AL.	
	Examiner	Art Unit	
	LESLIE R. DEAK	3761	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 January 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *16-24* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *16-24* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *16 April 2004* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

2. Claim 16 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 787 500 A1 to Wratten et al in view of US 5,571,418 to Lee et al.

In the specification and figures, Wratten discloses a hemofiltration device substantially as claimed by Applicant. With regard to claims 16 and 18, Wratten discloses a hemofiltration device comprising a first conduit 1 that directs a blood stream from a source 4 to a hemofilter 5, a second conduit 9 that directs the filtered blood stream back to the source 4, a third conduit 8 that directs the ultrafiltrate stream to an adsorption device 11/12 that contacts the ultrafiltrate stream with an adsorptive material to remove cytokines, which are inflammatory mediators, and a fourth conduit (unlabeled) that directs the postadsorptive ultrafiltrate back to the source (see FIG 1 and accompanying text).

Wratten fails to disclose that the conduits direct fluid to and from a mammal. Applicant's recitation that the conduits are "adapted to" perform a particular function are not a positive structural recitation but require only the ability to function as claimed. It has been held that a recitation with respect to the manner in which a claimed apparatus is intended to be employed does not differentiate from a prior art apparatus satisfying the claimed structural limitations. Applicant has not set forth any structural limitations

that accomplish the claimed function or differentiate from the conduits disclosed by Wratten. Furthermore, Wratten but discloses that fluid may be taken and returned to the patient using known means (see Wratten, p4, lines 10-20). Accordingly, the Wratten disclosure reasonably suggests to one of ordinary skill in the art that the disclosed conduits are capable of directing fluid flow between the locations claimed by applicant, satisfying the limitations of the claims.

Wratten does not specifically disclose the porosity of hemofilter 5, but does disclose that it has a small pore size. Lee discloses hemofiltration of toxic mediator-related disease comprising the steps of withdrawing blood from a mammal, filtering the blood, and returning the filtered blood to the patient (see Lee column 4, lines 32-39). The filter used by Lee may have a molecular weight exclusion limit of 100,000 to 150,000 Daltons, which is "greater then or equal to 69,000 Daltons" as claimed by applicant. Lee discloses that the larger Dalton filter (which is capable of allowing albumin to pass into the ultrafiltration stream) improves results over the prior art smaller pore filters (see column 2, lines 5-15, column 3, lines 15-31). Therefore, it would have been obvious to one having ordinary skill in the art at the time of invention to substitute the large pore filter disclosed by Lee for the hemofilter disclosed by Wratten in order to increase treatment effects, as taught by Lee.

With regard to claim 22, Lee discloses that the hemofilter may be made of polysulfone or polyamide (see column 1, lines 59-61).

With regard to claims 23 and 24, Wratten discloses that the adsorbent material may comprise activated carbon or polystyrene resins (see page 2, lines 40-66).

3. Claim 17 is rejected under 35 U.S.C. 103(a) as being unpatentable over EP 0 787 500 A1 to Wratten et al in view of US 5,571,418 to Lee et al, further in view of US 5,846,419 to Nederlof.

In the specification and figures, Wratten and Lee disclose the apparatus substantially as claimed by applicant (see rejection above).

With regard to claim 17, the cited prior art fails to disclose the merging of the first and fourth conduits to provide a combined post-treatment stream of fluid.

Nederlof discloses an extracorporeal blood treatment apparatus comprising a first conduit or patient blood supply line 82 that directs blood from a mammal to a blood filtration device 12, a second conduit 84/85 that directs fluid from the filter 12 back to the mammal, a third conduit 70 that directs ultrafiltrate from the filter to a second treatment apparatus 60, and a fourth conduit 72/85 that receives fluid from a second treatment apparatus and returns the treated fluid to the mammal. The second conduit 84 and the fourth conduit 72 merge at reservoir 78 to combine the post-treatment streams into a single stream supplied by conduit 85 for return to the mammal.

With regard to claims 19-21, the cited prior art fails to disclose a fifth conduit for splitting ultrafiltrate into a waste stream and a return stream, wherein the divider is a three-way joint. Nederlof discloses that discharge line 24 comprises a joint with line 52 and line 25 where ultrafiltrate is divided with some going to drain or waste container 90 (see FIG 1).

All the component parts of the instantly claimed invention are known in the prior art. The only difference is the combination of the known elements into a single apparatus by merging the return fluid lines disclosed by Wratten. This, it would have

been obvious to one having ordinary skill in the art to merge the second and fourth conduits disclosed by Wratten to form a single, combined fluid stream as disclosed by Nederlof, as well as use a fifth conduit and divider to divert some ultrafiltrate to a waste container, as disclosed by Nederlof, since the operation of the Wratten device is in no way dependent on the combination or diversion of the fluid stream for patient return, and the combined fluid stream is easily used in combination with a two-fluid return apparatus to achieve the predictable results of providing a combined fluid stream to the patient and discarding waste fluid.

Response to Amendment/Arguments

4. Applicant's amendment and arguments filed 23 January 2009 have been entered and considered.

5. Applicant's arguments drawn to the incompatibility of the Wratten and Lee references has been fully considered but is unpersuasive.

6. Applicant argues that the Examiner's reliance on the technical feasibility of the proposed combination is not a useful standard for obviousness. As stated previously, the Examiner is not looking to the physical combination of the Wratten and Lee devices, but rather the combined teachings of the references. It is the position of the Examiner that taken together as a whole, the references teach the extracorporeal tubing arrangement disclosed by Wratten and a filter with a pore size disclosed by Lee, which can be combined, with no change in the functions of the respective elements, to arrive at an extracorporeal circuit with a filter comprising a small pore size.

7. Applicant argues that the prior art does not suggest the combination of Wratten and Lee. A basis to combine teachings need not be expressly stated in any prior art reference. *In re Kahn*, 441 F.3d 977, 989 (Fed. Cir. 2006). There need only be an articulated reasoning with rational underpinnings to support a motivation to combine teachings. *In re Kahn*, 441 F.3d at 988. Furthermore, it has been held that the combination of familiar elements according to known methods is likely to be obvious when it does no more than yield predictable results." *KSR International Co. v. Teleflex Inc.*, 127 S.Ct. 1727, 1739 (2007). In the instant case, the Examiner is using the rationale postulated by the Court in *KSR* to provide the rational underpinnings required by the holding of *Khan*. Both the two-step operation of filtering blood and then filtering the ultrafiltrate to remove cytokines (as disclosed by Wratten) and a hemofilter with a small pore size (as disclosed by Lee) are known in the art. As such, it is the position of the Examiner that the combination of the elements of each disclosure would yield only the predictable result of a two-phase hemofiltration with a small initial pore size.

8. In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971). As set forth above, all the claimed elements of the invention were known in the prior art. While there is no specific suggestion in the art to combine the cited references,

one with ordinary skill in the art is presumed to have skills apart from what the prior art references explicitly say. *See In re Sovish*, 769 F.2d 738, 743 (Fed.Cir. 1985). A person of ordinary skill in the art is also a person of ordinary creativity, not an automaton. *KSR Int'l Co. v. Teleflex Inc.,* 127 S.Ct. 1727, 1742 (2007). Accordingly, it is the position of the Examiner that one with ordinary creativity would be able to modify the pore size of the filter in the Wratten device in order to create the claimed invention.

9. Applicant argues that Wratten and Lee teach away from one another. The Examiner disagrees. Applicant argues that since Wratten wishes to eliminate cytokines, one of ordinary skill in the art would not look to Lee, which has a larger pore size. Applicant argues that filters with much smaller pore sizes are suitable in the Wratten device. However, the Examiner notes that Lee specifically discloses that the filter with a larger pore size is an improvement over the prior art. The Applicant has not provided a specific instance in which either reference teaches that the elements of the proposed combination are unsuitable for one another. "The prior art's mere disclosure of more than one alternative does not constitute a teaching away from any of these alternatives because such disclosure does not criticize, discredit, or otherwise discourage the solution claimed.." *In re Fulton*, 391 F.3d 1195, 1201, 73 USPQ2d 1141, 1146 (Fed. Cir. 2004). Since Applicant has not pointed out that either reference discourages the claimed solution, nor how the references are medically incompatible, it is the position of the Examiner that the cited references do not teach away from one another.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to LESLIE R. DEAK whose telephone number is (571)272-4943. The examiner can normally be reached on Monday - Friday, 8:30am-5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Tanya Zalukaeva can be reached on 571-272-1115. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Leslie R. Deak/
Primary Examiner, Art Unit 3761
14 April 2009